

**REMARKS****Response to Double Patenting**

Claims 1, 40, 45 and 49 were rejected by the Examiner on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 & 7 of U.S. Pat. No. 7,322,938 in view of Tihon et al. (U.S. Pat. No. 5,415,656).

Applicants have filed concurrently a terminal disclaimer to moot this rejection.

**Response to Claim Rejections Under 35 U.S.C. §103**

Claims 1, 40-45 and 49-50 were rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over McGuckin, Jr. (U.S. Pat. No. 6,280,450) in view of Tihon et al. ('656). Claims 46-48 and 51 were rejected by the Examiner under 35 U.S.C. §103(a) as being unpatentable over McGuckin, Jr. ('450) in view of Tihon et al. ('656), and further in view of Grayhack et al. (U.S. Pat. No. 4,611,594).

McGuckin, Jr. describes a biopsy device in which the distal ends of the cutting elements (55) are secured to the distal tip (65) and the proximal ends of the cutting elements are secured to the distal end of the shaft (25). There is no distal shaft portion between the ends of the cutting elements in the McGuckin device. The cutting elements (55) are expanded by pushing on the shaft. It is unclear how the device works because pushing on the device to advance the distal end to the desired site would expand the cutting elements. Expansion of the cutting elements would seem to retard or prevent tissue penetration.

Tihon et al. on the other hand describes a device for performing a transurethral incision of the prostate (TUIP) which involves forming an incision in a patient's prostate to minimize the effects of benign prostate hyperplasia (BPH). No tissue is removed in the procedure. (See the attached article from WebMD regarding the TUIP). If a

problem-solution approach is taken, it would be clear that those having ordinary skill in the art would not look to devices for TUIP procedures for biopsy or tissue removal devices because there is no indication in the Tihon et al. reference that the device for performing the TUIP procedure operates in a manner suitable for tissue removal.

As noted in M.P.E.P. § 2141 "When considering obviousness of a combination of known elements, the operative question is this "whether the improvement is more than the predictable use of prior art elements according to their established functions" (Citing KKS International Co. v. Teleflex inc. 82 USPQ2d at 1396). In the Examiner's combination of McGuckin and Tihon et al. the elements of Tihon would not be used according to its established functions. One of the key features given in M.P.E.P. § 2141 for exemplary rationales is predictable results. However, there is no predictability that Tihon et al. device would work. Indeed, it is nothing more than speculation that the Tihon et al. device would be suitable in removing tissue. That being the case, applicants submit that the Examiner has not established a *prim facie* case for obviousness because the elements in combination do not perform the function that each element performs separately.

With respect to the rejection of claims 46-48 and 51, the Grayhack et al. reference fails to make up for the deficiencies of McGuckin and Tihon et al.

Applicants have amended the independent claims to more clearly indicate that the cutting element has one end secured to the distal shaft portion and one end which is movable with respect to the distal shaft portion by moving the one movable end toward the end secured to the distal shaft portion. This more clearly distinguishes the claims from the cited prior art.

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**Conclusion**

Applicants believe that the pending claims are directed to patentable subject matter. Reconsideration and an early allowance are requested.

Respectfully submitted,

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